

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

<b>RICHARD STREET,</b>	<b>:</b>	<b>Case No. 1:06-CV-17026</b>
	<b>:</b>	
<b>Plaintiff,</b>	<b>:</b>	
	<b>:</b>	
<b>v.</b>	<b>:</b>	
	<b>:</b>	
<b>LINCOLN ELECTRIC CO., et al.,</b>	<b>:</b>	
	<b>:</b>	
<b>Defendants.</b>	<b>:</b>	<b>Judge Kathleen M. O'Malley</b>
	<b>:</b>	
	<b>:</b>	<b><u>MEMORANDUM &amp; ORDER</u></b>
	<b>:</b>	

Currently pending is plaintiff Street's motion to strike certain opinions of Dr. James Mortimer (docket no. 160). For the reasons and to the extent stated below, the motion is **GRANTED in part and DENIED in part**. Accordingly, Street's related motion to bar certain testimony of Dr. Mortimer (docket no. 175) is **DENIED as moot**.

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Dr. Mortimer is defendants' retained expert in epidemiology and bio-statistics. He provided four expert reports in this case, referred to by the parties as follows: (1) his December 2009 "original report"; (2) his May, 2011 "first supplemental report"; (3) his June 2011 "meta-analysis report"; and (4) his June

2011 “second meta-analysis report.”<sup>1</sup> Street does not challenge admission of the opinions contained in the first two of these reports. Street does challenge the opinions contained in the latter two “meta-analysis reports,” arguing the reports were filed after the Court-imposed deadline. In their response brief, however, defendants explain that “Dr. Mortimer does not intend to rely on any opinions or data in [the second meta-analysis report], unless they are also contained in [the other reports].” Response at 4 n.3. Accordingly, the only expert report at issue is Dr. Mortimer’s June 2011 meta-analysis report.

The circumstances leading up to Dr. Mortimer’s submission of his meta-analysis report are as follows. On April 5, 2011, Street submitted a report from his expert neurologist, Dr. Juan Sanchez-Ramos. Among other things, Dr. Sanchez-Ramos opined that “[m]any epidemiological studies have revealed an association between exposure to manganese and various motor and neuropsychological deficits, including PD [Parkinson’s Disease] and early onset PD.”<sup>2</sup> Dr. Sanchez-Ramos cited about 23 epidemiological studies (“epi-studies”) which, he asserted, revealed this association, and also offered an explanation of why two other epi-studies did not reveal this association. Defendants and their counsel were intimately familiar with all of these studies, as these and other epi-studies have been cited repeatedly in motions and trials of earlier *Welding Fume* cases.

In response, defendants timely filed Dr. Mortimer’s first supplemental report. This report went into great depth regarding the strengths and weaknesses of each of the epi-studies cited by Dr. Sanchez-Ramos, including examination of the studies’ odds ratios – that is, whether the odds ratio was greater than one (thereby suggesting an association between manganese exposure and neurological disease), the confidence

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<sup>1</sup> Defendants also supplied to Street a fifth report by Dr. Mortimer, by mistake. Defendants state this fifth report, which is actually related to a different case, was not meant to expand the scope of Dr. Mortimer’s opinions in this case, so the fifth report is not at issue.

<sup>2</sup> Dr. Sanchez-Ramos’s declaration at 3 ¶11.

interval that surrounded the odds ratio (which reveals whether the odds ratio is statistically significant), and so on.<sup>3</sup> There is no question but that Dr. Mortimer's epidemiological analysis, as set out in his first two reports, is a thorough critique of Dr. Sanchez-Ramos's analysis and methodology.

After the parties had submitted their expert reports, defendants deposed Dr. Sanchez-Ramos. During this deposition, defendants asked Dr. Sanchez-Ramos about the epi-studies he cited, and to which ones he gave the most weight. Dr. Sanchez-Ramos responded as follows:

A. You know what I put the weight about epidemiological studies? How many of these epidemiological studies have odds ratios that are greater than one versus how many have odds ratios less than one.

Q. Regardless of the confidence interval?

A. Yes. Well, it's kind of a meta-analysis. Take out all of the epidemiological studies and plot the odds ratio, the point estimate, and you will see many more of the epidemiological studies, even though their conclusions are negative, no association, the odds ratio is to the right of no effect. And, theoretically, you should have equal numbers of negative associations and positive associations on both sides of one, and you don't, so that tells you there's fire where there's smoke. And that's where I – that's all I can really say about the epidemiology.

Depo at. 256-57.

It was Dr. Sanchez-Ramos's use of the phrase "kind of a meta-analysis" that led to defendants' submission, three weeks later, of Dr. Mortimer's meta-analysis report. In this report, Dr. Mortimer undertakes a complex statistical examination, combining certain epi-studies that examine whether there is an association between manganese exposure and neurological disease. Specifically, Dr. Mortimer: (1) identified all epi-studies that appeared to be on point; (2) determined whether any of these studies suffered a weakness that called for its exclusion from his combined statistical examination; (3) performed a meta-

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<sup>3</sup> The Court understands that some epi-studies reported odds ratios and some reported risk ratios. The distinction is not material for purposes of this opinion.

analysis of the remaining epi-studies, which is “a method of pooling study results to arrive at a single figure to represent the totality of the studies reviewed;”<sup>4</sup> and (4) arrived at a “pooled risk ratio” calculation. Dr. Mortimer ultimately concluded his meta-analysis showed “the probability that there is an increased risk” of a welder suffering Parkinson’s Disease is “less than one in a billion.”<sup>5</sup> Dr. Mortimer also presented several charts, known as “forest plots,” showing in graphic form the odds ratios and confidence intervals for the epi-studies he examined. These forest plot charts are relatively simple, making clear which epi-studies have odds ratios greater than one and which less than one, and also identify the “pooled risk ratio” for the studies listed in the chart.

With his pending motion, Street seeks to exclude Dr. Mortimer’s meta-analysis because it was submitted after the deadline for defendants’ expert reports.<sup>6</sup> For the reasons that follow, the Court concludes that part (but not all) of Dr. Mortimer’s meta-analysis opinions must be excluded at trial, given their content and timing.

Although Dr. Sanchez-Ramos referred to his review of the epi-studies he cited as a “kind of meta-analysis,” it was not that at all. A true meta-analysis, of the sort Dr. Mortimer performed, involves a sophisticated statistical review and mathematical synthesis: “Meta-analysis is a method of pooling study results to arrive at a single [odds ratio and confidence interval] to represent the totality of the studies

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<sup>4</sup> Federal Judicial Center, *Reference Manual on Scientific Evidence* at 380 (2<sup>nd</sup> ed. 2000).

<sup>5</sup> Meta-analysis report at ¶15.

<sup>6</sup> In his related *Daubert* motion (docket no. 175), Street argues the methodology Dr. Mortimer used is faulty and his opinions must be excluded as unreliable. The Court does not examine this argument.

reviewed.”<sup>7</sup> Dr. Sanchez-Ramos did not perform, or assert he performed, this sort of calculation; rather, he merely identified which studies reported odds ratios greater than one, and which reported odds ratios less than one. Given the history of this MDL, this odds ratio information was already well-known by Dr. Mortimer (and by virtually all of the parties’ other neurology and epidemiology experts) before Dr. Sanchez-Ramos even submitted his expert report.

Indeed, Dr. Mortimer acknowledged he had all the information necessary to perform a meta-analysis at the time he issued his first supplemental report. He believed a meta-analysis was not necessary, however, because, “if you look at the forest plot results, they are so uniformly to the left of 1.0.”<sup>8</sup> In other words, whereas Dr. Sanchez-Ramos believed there were “many more of the epidemiological studies [with an] odds ratio . . . to the right of no effect,” Dr. Mortimer believed the great majority of *relevant* epi-studies had odds ratios to the left of no effect, and Dr. Mortimer further believed it was not necessary to undertake a meta-analysis to counter Dr. Sanchez-Ramos’s opinion. It was only after Dr. Sanchez-Ramos incorrectly characterized his overview of the epi-studies’ odds ratios as a “kind of a meta-analysis” that Dr. Mortimer performed his own, more sophisticated statistical meta-analysis, to arrive at a “pooled risk ratio.” But Dr. Sanchez-Ramos’s “kind of a meta-analysis” was no more than a rough description of what he believed a forest plot would show.

Defendants cite Fed. R. Civ. P. 26(a)(2)(D)(ii) for the proposition that Dr. Mortimer’s meta-

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<sup>7</sup> *Id.* at 380-81; *see also id.* at 126 n.147 and 361 n.76. The Court expresses no opinion on whether the methodology Dr. Mortimer used to perform his meta-analysis passes *Daubert* muster, but it is clear his methodology employed the sort of statistical review to derive a pooled risk ratio generally contemplated by meta-analysis, unlike the methodology used by Dr. Sanchez-Ramos.

<sup>8</sup> Mortimer depo. at 257; *see id.* at 258 (agreeing that he “would be able to tell the jury why certain point estimates relied upon by Dr. Sanchez-Ramos that are to the right of 1.0 are inappropriate without doing a meta-analysis”).

analysis was *not* offered after any applicable expert report deadline, because the meta-analysis is purely rebuttal opinion.<sup>9</sup> Defendants note Dr. Mortimer delivered his meta-analysis opinion only three weeks after Dr. Sanchez-Ramos first used the term “meta-analysis,” and assert the supplemental opinion is therefore timely and appropriate. The Court might agree if, in fact, Dr. Sanchez-Ramos had actually performed a real meta-analysis and offered related opinions during his deposition; in that case, appropriate rebuttal could include a “competing” meta-analysis, and the parties could then argue regarding which methodology was better and more accurate.<sup>10</sup> As noted, however, Dr. Sanchez-Ramos did not perform a real meta-analysis; indeed, he did not even produce a written “forest plot” chart, although his overview brings one to mind.

Essentially, then, defendants rely on Dr. Sanchez-Ramos’s incorrect and fleeting characterization of his overview of the epi-studies to launch a full “rebuttal” meta-analysis – which, as Dr. Mortimer concedes, is not even necessary for him to explain to the jury why he believes Dr. Sanchez-Ramos’s overview is flawed. Dr. Mortimer’s 16-page meta-analysis report, and his “pooled risk ratio” calculation of “less than one in a billion,” goes well beyond merely rebutting Dr. Sanchez-Ramos’s review of which epi-studies are trustworthy and showed odds ratios greater than one; it offers new analysis and opinions. Because Dr. Mortimer’s meta-analysis report does not simply or “solely . . . contradict or rebut evidence

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<sup>9</sup> The cited rule states: “Absent a stipulation or a court order, [expert reports] must be [submitted] . . . , (ii) if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another [expert], within 30 days after the other [expert’s] disclosure.” Fed. R. Civ. P. 26(a)(2)(D)(ii).

<sup>10</sup> Actually, had Dr. Sanchez-Ramos offered a full meta-analysis and related opinions at his deposition, it is likely defendants would have moved to strike those opinions because they were not included in his expert report; and the Court would likely have either granted such a motion or allowed Dr. Mortimer to file a rebuttal expert report.

on the same subject matter,” and pursuant to the Court’s discretion under Fed. R. Evid. 611(a),<sup>11</sup> the Court concludes that virtually all of the opinions contained in Dr. Mortimer’s meta-analysis report must be stricken as untimely.

There is, however, an exception. The Court further concludes it is fair and reasonable for defendants to present at trial Dr. Mortimer’s opinions regarding forest plots, of the sort shown at pages 13-16 of his report (*without* pooled risk ratio conclusions). That is, Dr. Mortimer may: (1) present forest plots of epi-studies’ odds ratios; (2) explain why he believes only the epi-studies shown in these forest plots are the relevant studies; and (3) testify regarding what the forest plots show about the studies’ odds ratios individually and as a whole, and whether they show an association between manganese exposure and neurological disease. This testimony *is* fair rebuttal to Dr. Sanchez-Ramos’s epidemiology analysis, without going beyond it into meta-analysis. Further, allowing this testimony does not implicate any need by Street for additional deposition of Dr. Mortimer, since both he and Dr. Sanchez-Ramos discussed odds ratios and epi-study flaws in their original expert reports.

**IT IS SO ORDERED.**

/s/ Kathleen M. O’Malley

**KATHLEEN McDONALD O’MALLEY**  
**UNITED STATES DISTRICT JUDGE**

**DATED:** September 26, 2011

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<sup>11</sup> This rule directs the court to “exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to . . . avoid needless consumption of time . . . .” Fed. R. Evid. 611(a). The Court has no doubt that defendants can effectively and thoroughly cross-examine Dr. Sanchez-Ramos regarding his epidemiological opinions using only forest plot charts and other data, and without relying on a meta-analysis, having seen defendants do so at the *Daubert* hearing addressing Dr. Sanchez-Ramos’s opinions. Not only is defendants’ presentation of the meta-analysis unnecessary and beyond mere rebuttal, but its exclusion will also save the jury from having to hear arcane evidence and argument from Street regarding its alleged flaws.